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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,771	09/26/2003	Richard David Guarino	P-5840P1	4333
32330	7590	08/25/2005	EXAMINER	
DAVID W. HIGHET, VICE PRESIDENT AND CHIEF IP COUNSEL 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			TSAY, MARSHA M	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,771

Applicant(s)

GUARINO ET AL.

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,29-31,38,65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,29-31,38,65 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' election of Group V, claims 30-31, 38, 65-66, without traverse is acknowledged. Claims 2-28, 32-37, 39-64 are canceled. Claims 1, 29, 30, 31, 38, 65-66 are pending and currently under examination.

Priority: The benefit date is August 14, 2003, for the purpose of prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Glass et al. (1996 Biomaterials 17: 1101-1108). Glass et al. teach methods to covalently couple RGD-containing peptides to a cross-linked natural biopolymer, hyaluronic acid (HA) and the characterization of this peptide cell attachment matrix (p. 1101; claim 1). Glass et al. teach samples containing the HA-RGD peptide cell matrix are used in a cell attachment assay for MG63 human osteosarcoma cells. One mL of the MG63 cell suspension was mixed with samples of HA-RGD and placed on a rocking

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platform at 37°C/95% air/5% CO₂ for 30-60 min. (p. 1102; claim 29). At the end of the assay, the samples are transferred to 24-well dishes and non-bound cells removed by washing three times with phosphate-buffered saline (p. 1102; claim 30). For long-term growth of cells, the matrices containing attached cells were placed in DMEM containing 10% defined bovine serum and maintained at 37°C for 5 days (p. 1102; claim 30).

Claims 1, 29-31, 65-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayes et al. (US 6150459). Mayes et al. teach comb polymers for regulating cell surface interactions wherein a ^{hex} ~~pentamer~~ amino acid sequence (GRGDSP), was used to create adhesion ligand-bearing comb polymers by tethering the RGD to functionalized ends of PEG side chains (col. 20, lines 44-50). The mixtures of the activated comb polymers and the non-cell binding comb copolymers were prepared in various ratios, and cast from solution in toluene onto glass slides to prepare films of the adhesion ligand-bearing comb copolymers for cell culture (col. 20, lines 59-65; claim 1). In example 3, Mayes et al. teach NR6 fibroblasts transfected with wild-type human epidermal growth factor receptor (WT NR6) were cultured in modified Eagle's medium alpha (MEM- α) supplemented with nutrients (col. 20, lines 66-67). Cells were seeded at 20,000 cells/cm² onto comb copolymer films for 24 hours, followed by aspiration to remove unattached cells and application of fresh medium (col. 21, lines 4-10; claim 29-31). In example 5, Mayes et al. teach combs were used to create substrates which present co-tethered epidermal growth factor (EGF) and RGD (col. 21, line 60). Solutions of EGF were incubated on surfaces containing activated combs mixed with

the RGD combs (col. 22, line 10-13). Mayes et al. teach primary rat hepatocytes were cultured in the solution for 24 hours and were observed to adhere and spread on the mixed ligand surface (col. 22, lines 25-27; claim 30, 65-66).

Claims 1, 29-31, 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Brandley et al. (1988 Analytical Chemistry 172(270-278). Brandley et al. teach a synthetic nonapeptide (YAVTGRGDS), comprising the adhesive RGD sequence, was covalently immobilized on polyacrylamide gel surfaces. The surfaces derivatized with 2 nmol peptide/cm² gel supported long-term fibroblast growth (p. 270; claim 1, 38). Brandley et al. teach derivatized gels were washed in sterile medium and placed in the bottom of 24-cell culture plate wells prior to use. Brandley et al. teach the medium was removed from the derivatized gels and replaced with 0.5 mL of fibroblast cell suspension (p. 272; claim 29). Dishes were gently agitated to ensure even distribution of the cells and then placed in an incubator (p. 272; claim 29). The medium was removed from each well and replaced with fresh medium on the third and sixth days of culture (p. 272; claim 30-31). Brandley et al. teach the fibroblast adhesion to peptide-derivatized gels was determined using a centrifugation assay and Figure 1 illustrates the efficiency of the RGD derivatized gels' cell adhesion properties (p. 272; claims 29, 30-31, 38).

Claims 1, 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Campbell et al. (US 20030162289 A1).

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The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Campbell et al. teach peptides promoting cell adherence, growth and secretion that may be non-specifically adsorbed, or chemically attached to a surface or formulated in a culture medium to produce the desired effect on cultured cells. In examples 1-5, Campbell et al. teach peptides affecting cell adherence and growth for the cell line MC3T3-E1, a clonal line of murine calvaria-derived osteoblast cells (p. 8, [0080]; claim 1, 29-31). Campbell et al. teach cell maintenance in example 2 and the monitoring of cell growth in example 4 (p. 8). Growth was monitored at the following time points: 1 hour, 24 hours, 32 hours, 48 hours and 86 hours. Media was changed every three days (p. 9). In Figure 1 and Table 1, Campbell et al. show the inventive peptides promote the growth of MC3T3 cells wherein the peptide controls, polylysine and RGDSP, do not (p. 9, [0100]).

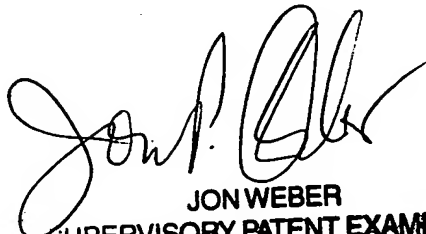
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 4, 2005


JON WEBER
SUPERVISORY PATENT EXAMINER